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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/973,576	04/02/1998	BERNARD MALFROY-CAMINE	15390-00013U	7067

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	20

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
08/973,576	Malfroy-Camine
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Aug 27, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see enclosed note

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*

Claim(s) objected to: *6 and 11*

Claim(s) rejected: *1-5, 7-10, and 12-22*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other:

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

1. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA
1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 14-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,4-12,24,29-33 of copending application Serial No. 08/483944 for the reasons elaborated in the previous Office Action.

Applicant has indicated that this issue will be addressed at a later date.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5,7-10,12-22,24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method or product using the lipid glycyldioctadecylamide, does not reasonably provide enablement for the claimed inventions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in

scope with these claims.

According to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Applicant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while applicant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

Regarding applicants comments, the MPEP section 2164.03 (Rev. 1, Feb. 2000) states:

However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999

F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

Applicant has already previously argued that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The instant specification only provides examples using a single type of lipid of a single size. According to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Applicant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while applicant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

Regarding the Malfroy-Camine declaration, paragraphs 7 and 8, according to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added

hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. Thus, applicant has already indicated that the Horan et al. reference is germane to the instant invention and the issue of whether length of the hydrocarbon chain can effect intracellular versus cell membrane localization. Furthermore, Horan et al. teach:

"In other applications, monoclonal antibodies, lectins, agonist or antagonists to tissue receptors, glycosaminoglycans, sialic acids or other molecules may be placed on the exterior surface of the cell to alter the migration patterns of the cell." (see column 5, second paragraph).

Thus, Horan et al. disclose that their teachings are relevant to a variety of different molecules, including antibodies. Regarding paragraphs 9 and 10 of the Malfroy-Camine declaration, applicant has already previously argued that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The instant specification only provides examples using a single type of lipid of a single size. According to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Applicant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while applicant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there

is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

5. Claims 6 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644